UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,703	07/25/2001	Darrell R. Anderson	27693-01008	4927

47553 7590 12/29/2006

SIDLEY AUSTIN LLP
ATTN: DC PATENT DOCKETING
1501 K STREET, NW
WASHINGTON, DC 20005

EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/911,703	ANDERSON ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,26,29-32,41-43,45-48,51-62 and 68-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,26,29-32,41-43,45-48,51-62,68-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 21,26,29-32,41-43,45-48,51-62,68-72 are under consideration.

2. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Applicants priority claim lacks the appropriate petition as per specified and required above.

3. The proposed correction to Figure 5 (amendment filed 8/12/05) is approved.

4 Petitions to correct inventorship were filed in parent application 08/149099 and other applications which claimed priority to said application wherein the contribution of the various inventors to various inventions originally claimed in said application was clarified. The inventorship in the instant application must be amended to be congruent with statements made in said petitions.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 21,26,29-32,41-43,45-48,51-58,60-62,68-72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,736,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of antibody claims differ in scope (claim 1 is limited in that the antibody is produced using a particular transfectoma which would influence certain characteristics of the antibody (such as glycosylation, etc)), the sequences recited in the antibody of claim 21 of the instant application are found in the antibody of claim 1 (the instant application is a continuation of the US application which yielded 5,736,137). Claims 2-5 disclose compositions containing the aforementioned antibody and a pharmaceutically acceptable carrier. The various radiolabels and chelator and dosages recited in the claims are obvious in view of the well established use of radiolabelled antibodies in the prior art. The antibody of claim 1 could be of any desire isotype depending on the particular use of the antibody. The particular dosages recited in the claims are encompassed by those recited in claims 4-6.

Applicant has agreed to file a terminal disclaimer at a later date.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 41,43,45-48,51-57,69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. The previously pending rejections as enunciated in paragraph 8 sections A), B) and D) of the Office Action mailed 4/7/05 are withdrawn in view of the cancellation of claims which have been cancelled, the amended claims and applicants arguments. The previously pending rejections as enunciated in paragraph 8 section C) (except as noted below) of the Office Action mailed 4/7/05 are withdrawn in view of the cancellation of claims which have been cancelled, the amended claims and applicants arguments.

C) There is no support in the specification as originally filed for the dosages of claim 54. Regarding applicants comments that the dosage finds support in the specification, page 17,line 25, said passage refers to a dosage of indium-111 for diagnostic use and is not a dosage for use with other isotopes or nondiagnostic use of indium.

There is also no support in the specification as originally filed for the limitation recited in claim 57. Regarding applicants comments that the dosage finds support in the specification, page 18, said passage refers to a single treatment dosage of Iodine 131 given at the specified dosage recited in the passage and is not a disclosure that encompasses use of other isotopes at unspecified concentrations.

AA) There is no support in the specification as originally filed for the "pharmaceutical carrier" of claim 41/69. Regarding applicants comments, the term "pharmaceutical carrier" is not disclosed in the specification as originally filed and differs in scope from a pharmaceutically acceptable buffer which is disclosed in the specification. Regarding applicant comments, "methods for preparing parentally administerable agents" is not a disclosure of the scope of a "pharmaceutical carrier". The pharmaceutical carrier encompasses carriers that are not used for parental administration. Furthermore, said phrase does not disclose use of pharmaceutical carriers per se. In addition as per 37 CFR 1.57 (c)(1), material essential to provide written description of the claimed invention must be incorporated by reference from a US Patent or application.

There is no written description of the scope of the claimed inventions in the specification as originally filed (eg. the claimed inventions constitute new matter).

9. Regarding priority for the claimed inventions and the application of prior art, for the same reasons that the inventions of claims 41,43,45-48,51-57,69 constitute new matter, they lack support in the various parent applications to which priority is claimed.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 41,43,45-48,51-57,69 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (US Patent 5,736,137).

Anderson et al. teach the chimeric IgG1 antibody C2B8 (see columns 21-24) wherein the antibody has the variable light and heavy sequences recited in the claims (see figures and sequence listing). 2B8 is the murine antibody from which the variable regions of C2B8 was obtained (see column 30). Anderson et al. teach 2B8 radiolabelled with yttrium-90 (see column 18). Anderson et al. teach yttrium-90 labeled C2B8 (see column 31). Anderson et al. use of the chelator MX-DPTA to radiolabel antibody with yttrium-90 or indium 111 (see column 7). Anderson et al. teach the aforementioned antibodies with a buffer (see column 8, first paragraph). Anderson et al. teach the intravenous administration of the aformentioned antibodies (see column 7, last paragraph) at a dosage encompassed by that recited in the claims (see column 8, second paragraph). Anderson et al. teach use of indium 111 radiolabelled antiCD20 antibody at a dosage encompassed by that recited in the claims (see column 9, penultimate paragraph).

12. Claims 21,26,41,42,58,59,69,70 are rejected under 35 U.S.C. 102(a) as being anticipated by Anderson et al. (1991).

Anderson et al. teach the chimeric IgG1 antibody C2B8 (see abstract) wherein the antibody has the variable light and heavy sequences recited in the claims (see specification). The murine antibody from which the variable regions of C2B8 was obtained is 2B8 (see specification). The antibody is expressed in mammalian cells wherein said antibody would inherently be found in tissue culture media (see third sentence).

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1600~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644